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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 10/602,694 | 06/20/2003 | Jean-Pierre Sommadossi | 06171.IDX 1006 CON1 | 8435 |

7590 04/06/2005

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EXAMINER

MCINTOSH III, TRAVIS C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1623

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,694

Applicant(s)

SOMMADOSSI ET AL.

Examiner

Traviss C. McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 130-148 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 130-148 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Detailed Action

The preliminary amendment filed 6/20/03 has been received and the specification and claims have been amended as requested.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 4, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 130-148 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 130-143 of copending Application No. 10/602,691. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to treating members of

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the Flaviviridae family with the same compounds. It is known that HCV is a member of the genus hepacivirus, and that hepacivirus, flavivirus, and pestivirus make up the family Flaviviridae, therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to treat flavivirus, pestivirus, and HCV with the same compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 130 and 132-148 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 89 and 130-174 of copending Application No. 10/602,693. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applicants are drawn to treating flavivirus or pestivirus infections using overlapping compounds. Particularly, both applicants require the compound to be a ribofuranosyl nucleoside wherein there is a methyl group in the 2' position (i.e., in the '693 application R⁶ is methyl; R¹ and R¹⁰ are H; R⁹ and R⁷ are OH; and the base is a purine). As such, the compounds intended to be administered overlap substantially.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 130-131 and 133-148 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,812,219 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to treating flavivirus or pestivirus infections

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using overlapping compounds. Particularly, both applicants require the compound to be a pyrimidine ribonucleoside comprising a methyl group in the 2' position. The compounds used in the instant application overlap substantially with the compounds used in the '219 patent.

Claim Objections

Claim 148 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 148 states that the flavivirus or pestivirus of claim 130 is not a hepatitis C virus, however, hepatitis C virus is not a flavivirus or pestivirus, and thus claim 148 adds nothing to the patentability of claim 130 as claim 130 is still drawn to treating only a flavivirus or pestivirus and therefor hepatitis C virus (HCV) is already delimited from claim 130. It is noted that HCV is a member of the genus hepacivirus, and since HCV is not a flavivirus or pestivirus, claim 148 is not seen to be limiting to claim 130.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,063,628 (Loeb et al.) which teaches modified bases of a ribonucleoside in viral treatment (see column 3, bottom paragraph). US 6,784,161 (Ismaili et al.) which teaches of modified ribonucleosides in viral treatment, as well as combination therapy using the same.

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Conclusion

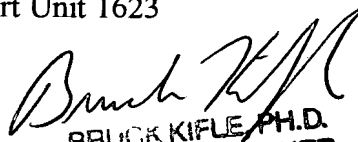
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh
March 31, 2005

 James O. Wilson
Supervisory Patent Examiner
Art Unit 1623


BRUCE KIFLE, PH.D.
PRIMARY EXAMINER